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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,400	06/04/2001	Werner G. Kuhr	407T-894701US	5307

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/03/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/874,400

Applicant(s)

KUHR ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Specification***

1. The disclosure is objected to because of the following informalities:

The first paragraph is objected to because it does not recite the U.S. Patent No. for Application No. 09/358,204.

Appropriate correction is required.

***Information Disclosure Statement***

2. The references listed on the 1449 received 4 June 2001 have been reviewed and considered. A copy of the signed 1449 is enclosed with this action.

***Claim Objections***

3. Claims 7 and 8 are objected to because of the following informalities: The claims appear to be missing the word "surface" at the of the claim.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1, 3-8 and 10-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (U.S. Patent No. 6,168,948 B1, filed 12 January 1998).

Regarding Claim 1, Anderson et al disclose a method of detecting two or more analytes in a sample comprising: providing a channel having affixed therein a binding partner for each of said two or more analytes wherein the binding partner for each of said analytes are located in different regions of the channel wherein the channel has a cross-sectional area small enough such that when analytes are released from said binding partners (Column 41, lines 31-58) wherein said analytes remain spatially segregated until they reach a detection point ins the channel downstream from the binding partners i.e. the method further utilizes capillary electrophoresis to analyze the analytes (Column 15, lines 10-12 and 26-32).

Regarding Claim 3, Anderson et al disclose the method wherein the channel is a capillary tube (Column 15, lines 26-32).

Regarding Claim 4, Anderson et al disclose the method wherein the capillary tube is a capillary electrophoresis tube (Column 15, lines 26-32).

Regarding Claim 5, Anderson et al disclose the method wherein the channel is a channel etched in a surface (Column 18, lines 54-58).

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Regarding Claim 6, Anderson et al disclose the method wherein the channel is etched in a glass surface (Column 18, lines 54-58).

Regarding Claim 7, Anderson et al disclose the method wherein the channel is a channel in a ceramic (Column 16, lines 8-10 and Column 20, lines 27-44).

Regarding Claim 8, Anderson et al disclose the method wherein the channel is a channel in a plastic (Column 19, lines 56-61).

Regarding Claim 10, Anderson et al disclose the method wherein the channel has a cross-sectional diameter of less than about 100 $\mu$ m (Column 30-34).

Regarding Claim 11, Anderson et al disclose the method wherein the channel has a cross-sectional width of less than about 500 $\mu$ m (Column 30-34).

Regarding Claim 12, Anderson et al disclose the method wherein the channel has a cross-sectional width of less than about 100 $\mu$ m (Column 30-34).

Regarding Claim 13, Anderson et al disclose the method wherein the two or more analytes comprise at least three different analytes i.e. total mRNA (Column 41, lines 22-30).

Regarding Claim 14, Anderson et al disclose the method wherein the binding partners are nucleic acids i.e. poly-t oligos (Column 41, lines 22-30).

Regarding Claim 15, Anderson et al disclose the method wherein the binding partners are nucleic acids i.e. poly-t oligos (Column 41, lines 22-30).

Regarding Claim 16, Anderson et al disclose the method wherein passing the fluid comprises fluid flow induced by a pressure difference Column 26, lines 1-7).

Regarding Claim 17, Anderson et al disclose the method wherein passing the fluid comprises electroosmotic fluid flow (Column 40, lines 47-54).

Regarding Claim 18, Anderson et al disclose the method wherein the sample comprises fluid selected from blood, plasma and oral fluid (Column 39, lines 10-12).

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, filed 12 January 1998).

Regarding Claim 2, Anderson et al teach a method of detecting two or more analytes in a sample comprising: providing a channel having affixed therein a binding partner for each of said two or more analytes wherein the binding partner for each of said analytes are located in different regions of the channel wherein the channel has a cross-sectional area small enough such that when analytes are released from said binding partners (Column 41, lines 31-58) wherein said analytes remain spatially segregated until they reach a detection point in the channel downstream from the binding partners i.e. the method further utilizes capillary electrophoresis to analyze the analytes (Column 15, lines 10-12 and 26-32) and they teach the analytes are "generally be labeled" (Column 11, lines 20-21) which suggests the analytes are sometimes not labeled. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use unlabeled analytes in the method of Anderson et al based on their suggestion and based on available detection apparatus for the obvious benefits of convenience and economy of time and labor by eliminating the labeling step and using available detection apparatus.

Regarding Claims 19 and 20, Anderson et al teach the method wherein the label is selected from radiolabel, biotin label, fluorophore label, gold particle label or any other detectable label (Column 1, lines 32-49) and they teach electronic detection (Column 15, lines 10-12) but they do not specifically teach the detection comprises absorbance spectroscopy and

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voltammetry. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to detect the spectroscopy and voltammetry detectable labels taught by Anderson et al and based on available spectroscopy and voltammetry detection apparatus and to detect the analytes using absorbance spectroscopy and voltammetry for the obvious benefits of convenience of using available detection apparatus.

Regarding Claim 21, Anderson et al teach the method wherein the analyte is amplified prior to detection thereby increasing the concentration of analyte (Column 8, line 61-Column 9, lines 14) but they do not teach detection of analytes at a concentration of less than  $10^{-9}$  M. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Anderson et al using routine experimentation to amplify the analytes whereby analytes having an original concentration of less than  $10^{-9}$  M are detected for the obvious benefits of detecting rare analytes and thereby accurately analyzing the sample for the presence of analytes.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent No. 6,168,948 B1, filed 12 January 1998) in view of Yager (U.S. Patent No. 6,007,775, issued 28 December 1999).

Regarding Claim 2, Anderson et al teach a method of detecting two or more analytes in a sample comprising: providing a channel having affixed therein a binding partner for each of said two or more analytes wherein the binding partner for each of said analytes are located in different regions of the channel wherein the channel has a cross-sectional area small enough such that when analytes are released from said binding partners (Column 41, lines 31-58) wherein said analytes remain spatially segregated until they reach a detection point ins the

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channel downstream from the binding partners i.e. the method further utilizes capillary electrophoresis to analyze the analytes (Column 15, lines 10-12 and 26-32) but Anderson et al are silent regarding a cross-sectional area that provides a Reynold's number of less than about 1. However, it was well known in the art at the time the claimed invention was made that channels having a Reynold's number of less than about 1 were desirable because a low Reynold's number provides laminar flow (see Yager, Column 4, line 59-Column 5, line5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cross-sectional area of Anderson's channels to provide a Reynold's number of less than about 1 for the obvious benefits of laminar flow i.e. facilitates analyte diffusion and detection as taught by Yager (Column 4, line 59-Column 5, line 14).

### ***Double Patenting***

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-46 of U.S. Patent No. 6.361.671. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting target analytes wherein binding partners are affixed in a channel, fluid comprising target is passed through the



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channel to bind respective binding partners, analytes are released from the binding partners and detected. The methods differ only in the arrangement of various claim limitations and in that instant Claims 9-12 recite channel dimension. However, the teaching within the patent defines their claimed channels as 33 $\mu$ m wide and 14 $\mu$ m deep. As such, the claimed patent channels are defined as being encompassed by the dimensions of Claims 9-12. The patent claims also differ from the instant claims in that the patent claims recite electrochemical detection while the instant claims broadly recite detecting. As such, the patent claim recite a detecting species while the instant claims recite a detecting genus. The courts have stated that a genus is obvious in view of the teaching of a species see *Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Therefore the instantly claimed analyte detection (i.e. genus) is obvious in view of the patent electrochemical detection (i.e. species).

### **Conclusion**

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
BJ Forman, Ph.D.  
Patent Examiner  
Art Unit: 1634  
September 25, 2002